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Trial record **1 of 54** for: BERT
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Temsirolimus, Bendamustine and Rituximab for Relapsed Follicular Lymphoma or Mantle Cell Lymphoma (BERT)

This study is currently recruiting participants.

Verified November 2009 by Johannes Gutenberg University Mainz

Sponsor:
Johannes Gutenberg University Mainz

Collaborators:
Wyeth is now a wholly owned subsidiary of Pfizer
Mundipharma

Information provided by:
Johannes Gutenberg University Mainz

ClinicalTrials.gov Identifier:
NCT01078142

First received: February 18, 2010
Last updated: June 24, 2011
Last verified: November 2009
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

This is a multicenter, open label, single arm, phase I/II study. There will be no placebo usage within this trial.

Phase I:

Primary: To establish a maximum tolerated dose of the addition of Temsirolimus to a regimen of Bendamustine and Rituximab (**BERT**) in patients with relapsed follicular lymphoma and mantle cell lymphoma.

Phase II:

Primary: To evaluate the ORR in patients with MCL or FL treated with the established **BERT** dose Secondary: To determine the complete remission rate, progression free survival rate and overall survival rate and to investigate safety and tolerability of **BERT**.

Condition	Intervention	Phase
Follicular Lymphoma Mantle Cell Lymphoma	Drug: Temsirolimus, Rituximab, Bendamustin	Phase 1 Phase 2

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase I/II Trial to Evaluate the Safety, Feasibility and Efficacy of the Addition of Temsirolimus to a Regimen of Bendamustine and Rituximab for the Treatment of Patients With Follicular Lymphoma or Mantle Cell Lymphoma in First to Third Relapse

Resource links provided by NLM:

MedlinePlus related topics: Lymphoma

Drug Information available for: Bendamustine hydrochloride Bendamustine Sirolimus Everolimus Temsirolimus Rituximab

U.S. FDA Resources

Further study details as provided by Johannes Gutenberg University Mainz:

Primary Outcome Measures:

- Phase I: MTD / Phase II: ORR [Time Frame: Phase I: 2 months (start cycle 3), Phase II: 6 months] [Designated as safety issue: Yes]
  phase II: ORR is evaluated approx. 6 weeks after end of treatment

Secondary Outcome Measures:

- Progression free survival [Time Frame: at 2 years] [Designated as safety issue: No]

  for part II only

Estimated Enrollment:	72
Study Start Date:	January 2010
Estimated Study Completion Date:	December 2014
Estimated Primary Completion Date:	March 2014 (Final data collection date for primary outcome measure)

Intervention Details:

Drug: Temsirolimus, Rituximab, Bendamustin

Phase I:

Temsirolimus 25 - 50 - 75mg, day 1,8,15 Bendamustin 90/m2, day 1,2 Rituximab 375/m2, day 1 Phase II at established dose, repeat day 28-42 (max)

Other Name: Mabthera, Rituxan, Torisel, Bendamustin, Ribomustin, Trenda

Detailed Description:

The first part of the study is a phase I study in which the maximum tolerated dose of the combination of Temsirolimus, Bendamustine and Rituximab will be established. In the phase I part of the trial 3 patients will be included in each dose level. After inclusion of 3 patients, each patient has to receive at least 2 complete cycles without DLT until the enrolment into the next cohort can be initiated. In case of one DLT, 3 additional patients will be added to the specific dose level. If a second DLT appears, the last dose level without DLT will be considered the standard dose for the phase II trial. If the third dose level is achieved without any DLT, there will be no further dose escalation.

In the phase II proportion of the trial, after establishment of a maximum tolerated dose, the efficacy of the combination regimens in two different patient cohorts will be evaluated. In the one cohort, 30 patients with relapsed mantle cell lymphoma will be treated; the second cohort will be composed of 30 patients with relapsed follicular lymphoma.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically proven diagnosis of follicular non-Hodgkin's lymphoma grades I, II or IIIA or mantle cell lymphoma (including Cyclin D1 expression) according to the World Health Organization classification
- Documented relapse or progression following at least one but not more than 3 antineoplastic treatments
- At least 1 measurable tumor mass (>1.5 cm x >1.0 cm) or bone marrow infiltration
- Subjects 18 years or older
- Status post. high dose therapy or no transplantation option available or patient refuses an aggressive treatment strategy
- Subjects (or their legally acceptable representatives) must have signed an informed consent document indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study
- Adequate bone marrow reserve: Platelets of at least 75000/µl, absolute neutrophil count at least 1500/µl. In case of extensive bone marrow infiltration and lower platelet or absolute neutrophil counts, patients can not be included in the phase I part of the trial. In the phase II proportion of the trial patients may be included with a platelet count of more or equal to 50000/µl on the discretion of the investigator, if thrombocytopenia is associated with massive bone marrow infiltration.
- Adequate hepatic and renal function
  - Alanine aminotransferase <2.5 x upper limit of normal (ULN); Aspartate aminotransferase <2.5 x ULN, Total bilirubin <1.5 x ULN
  - Measured or calculated creatinine clearance >50 mL/min
- Eastern Cooperative Oncology Group [ECOG] performance Status 0-2
- Female subject must be postmenopausal (for at least 6 months), surgically sterile, abstinent, or, if sexually active, be practicing an effective method of birth control (e.g., prescription oral contraceptives, contraceptive injections, intrauterine device, double-barrier method, contraceptive patch, male partner sterilization) before entry and throughout the study; and have a negative serum ß-hCG pregnancy test at screening

Exclusion Criteria:

- Lymphoma other than MCL or FL
- Active central nervous System lymphoma. Brain MRI is required only if clinically indicated
- Pregnancy or breast feeding women
- Severe concomitant disease (e.g. uncontrolled arterial hypertension, heart failure (NYHA III-IV), uncontrolled diabetes mellitus, pulmonary fibrosis, uncontrolled hyperlipoproteinemia)
- Active uncontrolled infections including HIV-positivity, active Hep B or C
- Mental status precluding patient's compliance
- Comedication with strong CYP 3A4/5-inhibitors or -inducers (Appendix 22.7)

- Prior treatment with Temsirolimus
- Known CD20 negativity
- Patients refractory to Bendamustine in a prior treatment line, defined as relapse within 1 year after initiation of first cycle. Exception: termination of treatment prior to third scheduled cycle for reasons other than toxicity.
- Status post allogeneic transplantation
- Peripheral neuropathy or neuropathic pain of Grade 2 or worse
- Diagnosed or treated for a malignancy other than NHL except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, DCIS of the breast, or other solid tumors curatively treated with no evidence of disease for >5 years
- Concurrent treatment with another investigational agent. Concurrent participation in non-treatment studies is not excluded.
- Known intolerance to sirolimus or derivates, or Bendamustine or Rituximab.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01078142

Contacts

Contact: Georg Hess, MD 00496131175040 georg.hess@unimedizin-mainz.de

Locations

Germany

Universitätsmedizin Mainz **Recruiting**
Mainz, Rheinland-Pfalz, Germany, 55131
Contact: Georg Hess, MD 00496131175040 georg.hess@unimedizin-mainz.de
Principal Investigator: Georg Hess, MD

Sponsors and Collaborators

Johannes Gutenberg University Mainz

Wyeth is now a wholly owned subsidiary of Pfizer

Mundipharma

Investigators

Principal Investigator: Georg Hess, MD Department of Hematology, Oncology and Pneumology, Universitätsmedizin der Johannes Gutenberg-Univers

More Information

Additional Information:

homepage study department PI EXIT

No publications provided

Responsible Party:	Georg Hess, MD, Universitätsmedizin der Johannes Gutenberg-Universität, Mainz, Germany
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Keywords provided by Johannes Gutenberg University Mainz:
temsirolimus
bendamustine
rituximab
mantle cell lymphoma
follicular lymphoma

Additional relevant MeSH terms:

Lymphoma	Antineoplastic Agents
Lymphoma, Follicular	Therapeutic Uses
Lymphoma, Mantle-Cell	Pharmacologic Actions
Neoplasms by Histologic Type	Antineoplastic Agents, Alkylating
Neoplasms	Alkylating Agents
Lymphoproliferative Disorders	Molecular Mechanisms of Pharmacological Action
Lymphatic Diseases	Antibiotics, Antineoplastic
Immunoproliferative Disorders	Antifungal Agents
Immune System Diseases	Anti-Infective Agents
Lymphoma, Non-Hodgkin	Immunosuppressive Agents

Bendamustine
Rituximab
Nitrogen Mustard Compounds
Sirolimus
Everolimus

Immunologic Factors
Physiological Effects of Drugs
Anti-Bacterial Agents
Antirheumatic Agents

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